



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/321,247 | 05/27/1999 | SI-YI CHEN | 0443-2U2 | 6190 |

28977 7590 03/31/2004

MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

EXAMINER

SULLIVAN, DANIEL M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1636

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/321,247

Applicant(s)

CHEN ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,14,16-19,23,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,14,16-19,23,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 February 2004 has been entered.

Claims 1-24, 29, 33, 34, 38 and 39 were pending and under consideration in the previous Office Action, mailed 9 May 2003. Claims 2, 8-13, 15, 20-22, 24, 29 and 33-34 were canceled and claims 1, 3, 14, 17, 19 and 23 were amended in the 17 February Paper. Claims 1, 3-7, 14, 16-19, 23, 38 and 39 are presently pending and under consideration.

Double Patenting

The provisional rejection of claims 1, 5-7, 14, 16, 18, 19 and 38 under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims of US Patent application 09/332,275 is withdrawn in view of the abandonment of the '275 application.

Response to Amendment

Claim Rejections - 35 USC § 112

Claims 1, 3-7, 14, 16-19, 23, 38 and 39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record.

The claims have been amended such that they are now limited to products and methods of using an expression vector comprising chemokine encoding regions which bind to HIV

Art Unit: 1636

accessory receptors. However, the record clearly indicates that the disclosure is not enabling even for this scope (*e.g.*, the fourth paragraph of the “Continuation of 5” section of the 9 May Office Action).

In the remarks that accompany the present amendment, Applicant asserts, “the Examiner contends that the specification does not teach an expression vector comprising any chemokine encoding region and any chemokine receptors” (page 5) and indicates that the claims have been amended in a good faith effort to expedite prosecution. The remarks contain no rebuttal of the Examiner’s contention that the claims are not enabled over any scope. Therefore, the claims properly stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for reasons already of record.

Furthermore, in a recent article, Onai *et al.* (2000) *Blood* 96:2074-2080 teach that *ex vivo* expression of an SDF-1 intrakine in bone marrow-derived hematopoietic progenitor cells and transplantation of the modified cells in mice resulted in impairment of lymphopoiesis and myelopoiesis (see especially the sections entitled “B lymphopoiesis in reconstituted mice” and “T lymphopoiesis in reconstituted mice”). Thus, the only description of record of the *ex vivo* method contemplated in the instant specification completely reduced to practice resulted in impairment of lymphopoiesis and myelopoiesis. Clearly, such an effect would not provide an increased white blood cell count or an effective therapy for HIV infection as contemplated in the instant application. Therefore, the findings of Onai *et al.* provide additional evidence as to the unpredictability of using the claimed products and methods for the purposes contemplated in the disclosure.

Art Unit: 1636

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS


DANIEL M. SULLIVAN
PRIMARY EXAMINER